Administrative Office
111 West Monroe,
Suite 510
Phoenix, AZ 85003

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A public-private coalition of individuals, entities and companies conducting business across U S. borders/ Una coalición de individuos, entidades y compañías que comercian através de las fronteras de los Estados Unidos/ Un regroupment de personnes, de compagnies et d'autres entités qui traitent des affaires transfrontalieres avec les États-Unis

Web Page
http://www.thebta.org

Toll Free/Sans-frais
U.S & Canada
(México, Agregar "001")
800-333-5523
Tel/Tél· 602-266-7427
Fax: 602-266-9826

BTA

Border Trade Alliance • Alianza del Comercio Fronterizo • Alliance du Commerce Transfrontalier

April 3, 2003

Dockets Management Branch (HFA-305)
Food and Drug Administration
5630 Fishers Lane, Room 1061
Rockville, Maryland 20852
ATTN: Docket No. 02N-0278

Re: Border Trade Alliance public comments on the Bioterrorism Act of 2002, Title III; Subtitle A, Section 305 (Registration) and Section 307 (Prior Notice)

Dear Sir or Madam:

The Border Trade Alliance (BTA) thanks the Food and Drug Administration for the opportunity to participate in the public comment period relating to FDA's plans for implementing the Public Health Security and Bioterrorism Preparedness and Response Act of 2002 (the Bioterrorism Act). Founded in 1986, the BTA serves as a voice for the cross-border trade community and the communities of the shared U.S.-Canada and U.S.-Mexico borders. In this post-September 11th environment, BTA supports the federal government's efforts to secure our borders while fostering a legitimate trade and travel-friendly environment. We agree with Homeland Security Secretary Tom Ridge's statement that economic security equates with national security, a philosophy we see as potentially undermined by FDA's proposed regulations.

As it relates to the Bioterrorism Act and FDA's proposed rules, the BTA is primarily concerned with legislative language relating to the importation of food across our land borders and registration of importing agents, thus our comments here will be limited to Sections 307 and 305 of the proposed regulations.

Section 307, Prior Notice

In the regulations as proposed, FDA requires that importers or purchasers of food notify FDA of their importation by noon the day prior to the food's arrival at the U.S. port of entry. In responding to this proposal, BTA comments as follows:

- With the exception of the exact arrival time, all of the information mandated by FDA is currently available when the entry is transmitted at time of importation. Congress seems to have misunderstood FDA's powers regarding the importation of foodstuffs. As it stands now, no imported foodstuff is allowed into the stream of commerce until it is authorized for distribution by the FDA. By making the import process so much more complicated, it encourages those who wish us harm to conceal the nature of their importations by not identifying them as foodstuff but as something else. We prefer not to

lay out in detail ideas which "bad guys" might rely upon. Suffice it to say a terrorist need only corrupt an existing shipper or carrier of manufactured goods and rely on his existing good record as a means to evade these new requirements.

- Given the current limitations of staffing, it will be impossible for FDA to thoroughly conduct a risk management analysis on the 20,000 daily submissions it expects to receive without a sophisticated computer system. The experiences of the FAA, IRS and Customs make clear it is impossible for a federal agency to build a computer system of the sort needed in the time allowed. FDA would be better served to work closely with Customs to identify risk factors and arrange for Customs to include those risk factors in its pre-arrival shipment profiling currently underway. Except for arrival information, we understand FDA already receives all the information it needs into OASIS from ABI, but is unable to receive arrival information from Customs AMS system. We recommend FDA direct its resources to making the necessary modifications to the Customs' current ACS system, until FDA's full integration into ACE.

- If indeed data must be transmitted prior to arrival, then instead of creating a new computer system and a requirement for duplicate transmission of data into a new system which lacks checks or edits, it makes more sense (economically and practically) for FDA to require transmission of entry information prior to arrival (we withhold comment as to the amount of time until later). If indeed there is a question whether such action by FDA would compromise the Customs requirements regarding entry pre-filing, then coordination between the agencies is in order, rather than a costly and likely unworkable new system being created.

- As currently proposed, the Prior Notice computer system will have no edits or checks. It will simply accept whatever data is transmitted. The old adage of GIGO comes to mind and leads inevitably to the likelihood that FDA will spend massive amounts of time trying to reconcile what it has been given as part of the pre-arrival process with what is in OASIS. Frankly, such efforts will seriously compromise the agency's ability to properly screen incoming goods. It is already horribly short-staffed and cannot keep up with the current flow of information and goods. The regulation as proposed will undermine the agency's efforts even more.

- Further, BTA views with some concern ambiguity surrounding the ability of importers to issue updates and amendments to their notices to FDA of an arriving food shipment. In the sphere of international trade, the importer and exporter always anticipate changes and we recommend FDA maintain appropriate flexibility as well. One change in each category is simply unrealistic. For example, the Fresh Produce Association of the Americas has pointed out a number of legitimate reasons a change in pre-notification might be needed. We would add another. It is not unheard of for there to be equipment failures coupled with changes in plans. It is the norm for larger companies to have arrangements/contracts with specific trucking operations. However, when there is a greater quantity of cargo to move than that transport operation can handle on a given day, independent owner-operators will be hired. The need for that service is generally not known by the day before importation, much less by noon the day before.

  Further, it is not unheard of for a truck to breakdown. As currently written, something as simple as the mechanical failure of a truck would require that load to sit an additional day because a change in carrier is not considered either an update nor an amendment. As a side note, we question why FDA even needs to know the identity of the carrier. We can find no language in the Act which authorizes such information as a data element. In fact, requiring it simply duplicates Customs' own requirements, and Customs is in a much better position to evaluate risk as relates to carriers and

already has in place programs which distinguish between secure carriers (such as the Land Border Carrier Initiative) and others.

- In determining which data elements should be collected, the BTA urges FDA to establish an evaluation process to determine the relevancy of each data element in thwarting possible bio-terrorism. In an effort to promote public-private dialogue in the creation of these criteria, allow us to suggest the model of COAC, the Treasury Department's Commercial Operations Advisory Committee. In the Customs' context, private sector COAC members work with Customs officials in crafting the rules that work effectively for both the agency and the international trade community.

- Paramount in FDA's approach to issuing regulations in order to comply with the Bioterrorism Act is the critical need for FDA and the various federal inspectional agencies to coordinate their efforts.

  The recent establishment of the Department of Homeland Security absorbed some agencies posted at our ports of entry, while leaving others untouched. In the need to keep our borders and supply chain secure, BTA recommends that FDA consult and coordinate with Customs as that agency works through its own experience with proposed prior notice rules. As you may know, U.S. Customs recently concluded a public comment period regarding the advance submittal of manifest information for shipments bound for a U.S. port of entry. In addition, Customs has worked closely with industry to find rules and procedures which are workable, following its attempt to unilaterally impose rules in the ocean context which have slowed trade to a crawl. At the Port of Los Angeles/Long Beach alone, a container used to move once every 11 seconds, 24 hours a day, seven days a week. Because of the "24-hour rule," what once took hours is now taking five (5) to seven (7) days to move. Does FDA really want to find itself the cause of such a catastrophe when it comes to the nation's food supply? The longer food sits, the more likely it is to spoil, deteriorate in quality, and/or become contaminated with harmful pathogens which are undetectable without extensive laboratory analysis.

- FDA is proposing that the importer provide advance notice on noon the day prior to arrival. Customs, on the other hand, sought to receive advance manifest notification four hours prior to arrival in the land border/truck environment. These two contrasting timeframes underscore the need for the agencies to coordinate their efforts and present a consistent and workable process to trade and industry.

  As we stated in our response to U.S. Customs, we are uncomfortable advocating any time frame for prior notice since we think the final decision should be made by the FDA working with the local border communities (north and south) on an expedited basis to determine a realistic time frame. However, if forced to state a time frame at this early stage of the discussion, we contend that advance notification of no more than one hour prior to arrival should be the norm in the land border context.

  The reason FDA gave for requiring the amount of advance notice proposed was to allow it to have its personnel in place to meet shipments. It is our understanding FDA already mans all the "usual" points of crossing for food so that justification seems inapposite for Canada-US and US-Mexico trade.

- We are concerned that in its laudable effort to secure the U.S. food supply, FDA has failed to focus on extracting accurate information from the import community, and instead has focused on a seemingly arbitrary timeframe for prior notice.

We commented above how the lack of edits/checks in the proposed Prior Notice computer system will likely lead to conflicting information with that in OASIS and how the agency will drown under the attempt to reconcile those discrepancies.

In addition, we suggest FDA consider development of a program that creates an incentive for reliable importers who operate in a secure environment and adhere to certain parameters set forth by FDA, Customs, or any of the other agencies dealing with security. A similar program established by U.S. Customs, the Customs-Trade Partnership Against Terrorism (C-TPAT), could serve as a model. The idea behind C-TPAT is that if one makes the effort to have a secure supply chain, there should be rewards. While Customs maintains the right to and does examine all sorts of containers, including those imported by C-TPAT members, if a C-TPAT member's cargo is examined, it is given priority to the head of the line. Something similar should be included as part of FDA's risk management approach. Further, when FDA enacts such a program, we encourage the agency to make the program's incentives available to importers both large and small.

- Additionally, regardless of whether we are discussing manufactured dry goods or foodstuffs, today's international trade operates in a just-in-time (JIT) environment, where, in an effort to keep overhead and expenses low, production corresponds as closely as possible with demand.

  Recognition of JIT is critical when dealing with perishable goods. The maxim that cargo at rest is cargo at risk takes on even greater importance when dealing with items whose shelf life will be significantly reduced if delayed at the U.S. border. Decreased shelf life leads to increased prices, which, in today's economy, is undesirable for all of us. Equally important, decreased shelf life leaves fertile situations for bacteria and other contaminants to grow while the cargo sits at produce sheds or on the side of the road waiting to cross.

  In enacting these regulations, for them to be a success, FDA must give realistic consideration to the way in which companies operate. If the amount of time cargo is going to be held by truckers and others increases, then their risk for loss or damage increases. Hence, cost goes up and they will be forced to build larger holding facilities. If the risk for loss or damage increases, so does the risk for compromise of the foodstuff. Similarly, these newly built larger facilities also become targets of opportunity, whether for terrorists, bandits, drug lords, or other criminals.

  Another area of concern for us is the amendments and updates. We have already discussed how we consider one of each to be an unrealistic limitation. By way of example, we note that changes in quantity require an amendment. For those products subject to USDA clearance, it is often necessary to unload those goods and then reload them. Trucks carrying such fruits and vegetables often gas-up to make sure they can make it to their next destination. Given that each state has different road weight limits, the amount of a given fruit or vegetable that can be loaded on a given truck changes with the weight of the truck. Therefore, when these items are loaded at locations near the border, one cannot anticipate what will go on which truck or in what quantity until appropriate weights and balances are considered. As a result, by allowing only one amendment and requiring that it be transmitted no later than two hours prior to arrival, FDA mandates that recently loaded truck to sit by the side of the road waiting for the FDA prior notice period to expire. By so doing, no only does FDA put the load at risk, it also contributes to contaminating the environment as the particulates from the truck spoil the air.

We turn next to something implied in FDA's proposal. It would appear FDA selected two hours as the minimum time frame for amendments on the mistaken assumption that all farms are further away and so two hours was not a problem. In point of fact, the vast majority of the farms in Mexicali and some places in Mexico near the Texas border are within two hours of the border. In short, those farms will now be required to harvest and pack their fruits and vegetables and leave them sitting in trucks until the prior notice period expires. Given that they will not know until the truck is sealed the exact nature of what will be shipped, that truck will sit for at least a couple of days (the day of packing plus the next day as transmission will not have occurred before noon the first day) and then the truck must wait until the following day to enter). If carrying a load subject to USDA inspection, that truck could be further delayed due to the repacking process mentioned above. In other words, the load in that truck could be stuck for four days before it can cross, the two necessitated by the original prior notice transmission, and an additional two when the repacking occurs because it will most likely not be completed in time for a transmission before noon on the first day.

We contend FDA and the trade community would be better served by the regulations allowing a variance in quantity and weight. This is again an area where we think FDA would be well served to work with the local communities to set a realistic percentage, but for lack of a better framework, we contend a variance of 20% should be allowed.

Finally, we take exception to FDA's conclusion that the U.S. importer always knows what he is receiving and thus transmission of data the day before is realistic. While it may be true that prepared and preserved items are clearly identified at time of order placement, that same maxim does not always hold when dealing with fresh items, such as fruits, vegetables, fish, etc. In the case of fruits and vegetables, these shipments are generally controlled by the Mexican exporter and by weather and events beyond the control of the shipper. Many of these shipments are on consignment to a U.S. based third party who acts as the agent of the exporter in selling them in the U.S. marketplace. Therefore, with those shipments, the importers do not know what they are getting until it arrives at their door. Harvesting can be the subject of delays caused by weather as well. Further, in the case of fish freshly caught, no one really knows the details of the catch until it is off-loaded and weighed and at that point is ready for movement. None of these events can be realistically predicted by noon the day prior to shipment.

Section 305, Registration

While our primary concerns relating to the rulemaking process surrounding the Bioterrorism Act center on the prior notice proposal, BTA does take some interest in Section 305 as it relates to the registration provisions.

In its proposal, FDA seeks to make whoever transmits information to the agency to be responsible for the accuracy of that information. While BTA appreciates FDA's efforts to affix responsibility for data transmittal, it is unrealistic for ultimate responsibility to rest with a U.S. agent who may have received unreliable information from a foreign supplier which, even with the exercise of due diligence, cannot be identified in advance as unreliable. After all, the U.S. agent is just that: an agent. He is only as good as the information provided by his principal. Therefore, we view FDA's position as questionable under the basics of principal-agency law. We think that so long as the agent does not self-blind (fail to identify obviously unreliable information) and does accurately report the data he is given, he should be found to have discharged his obligations.

Finally, BTA views the October 17, 2003 deadline for implementation of this system as overly ambitious. We encourage FDA to have a backup system in place which does not involve manual review of all submission and will still allow compliance with the Bioterrorism Act should the agency be unable to get the Prior Notice system fully operational in time. Trade-industry experience with the development of systems such as ACE (Automated Commercial Environment) and the maintenance of declining systems such as ACS (Automated Commercial System) suggests that endeavors such as the one proposed by FDA can be extremely time and labor intensive and simply do not work properly from the outset. Contingency plans should be established in order to ensure that system functions as expected and that any emergencies or unforeseen events are effectively managed in a commercially realistic time frame.

Once again, the BTA appreciates the opportunity to work with FDA in keeping the U.S. food supply secure while expediting the flow of legitimate commerce. Our organization offers its years of collective knowledge of cross-border affairs as FDA addresses these important issues.

Sincerely,

Richard Cortez
Chair

Stephen Birdsall
Chair, Agribusiness and Fisheries Committee

Dr. C. Parr Rosson, III
Co-Chair, Agribusiness and Fisheries Committee

Susan Kohn Ross
Chair, Ports of Entry Committee